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EXAMINER

HINES, J

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

10
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/306,780

Applicant(s)

Takamura et al.

Examiner

Ja-Na Hines

Group Art Unit
1641



☒ Responsive to communication(s) filed on May 18, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 17-32 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 17-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Amendment Entry

1 The amendment filed May 18, 2000 has been entered. Claims 17, 23-24 and 31-32 have been amended. Examiner also acknowledges amendments to the specification. Claims 17-32 are pending.

Priority

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Response to Arguments

3. Claims 23 and 24 are objected to because of the informalities is withdrawn in view of applicants amendments.

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4. Applicant's arguments filed May 18, 2000 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Weiner et al., is maintained. Applicant argue that there is no suggestion to combine the references because Weiner et al., does not indicate what would happen to the antigenic properties of the polypeptides, however the claims do not recite any language requiring the polypeptides to retain any particular properties. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious at the time of applicant's invention to have used the biologically active polypeptide linked to an amino acid donor having the ability to bind a nucleic acid as taught by Takahara et al., with the immunoassay as taught by Weiner et al., because Weiner et al., teaches polypeptides expressed in the form of a fusion polypeptide by genetic engineering, wherein the polypeptide is an antigen can be assayed in an immunoassay.

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Applicant argues the agglutination effect may be easily disrupted by the presence of DNA and may prevent agglutination in view of Weiner et al. The rejection claims 17-22 as being unpatentable over Takahara et al., in view of Weiner et al., are not drawn to agglutination assays, these claims are drawn to any form of immunoassay because these claims do not specify a particular type of assay. In response to applicant's argument that the references fail to show agglutination properties of applicant's invention, it is noted that the features upon which applicant relies i.e., agglutination ability are not recited in the rejected claims. Further, applicant merely suggest that the nucleic acid-bound polypeptide of Takahara et al., in view of Weiner et al., will not work in an agglutination assay without providing any evidence. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Weiner et al., in further view of Ono et al., is maintained. Takahara et al., and Weiner et al., have been discussed above. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious at the time of applicant invention to have used the Ono

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et al., hepatitis virus sequence, in the immunoassay of Takahara et al., and Weiner et al., because Ono et al., teaches the complete nucleotide sequence which is important in the understanding of the genetic system.

7. Claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Gibbons is maintained. Takahara et al., has been discussed above. Applicant argues that there is no suggestion to combine the references because the references fail to show certain features of applicant's invention. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, it would have been obvious to use the agglutination assay of Gibbons with the antigen comprising a nucleic acid bound polypeptide as taught by Takahara et al., because Gibbons teaches binding pairs include antigens and antibodies or complementary nucleic acid strands; that agglutination assays do not require expensive detection equipment; and can be readily adaptable to instrumental quantitation.

Applicant argues that Gibbons et al., teaches that the presence of DNA in the assay involves complementary nucleic acid strands and the present invention has a single nucleic strand bound to a polypeptide antigen without necessarily having a complementary DNA strand present. In response to applicant's argument that, it is noted that the features upon which applicant relies

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(i.e., the single nucleic strand) are not recited in the rejected claims and Gibbon et al., teaches other types of binding besides with a complementary strand. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

8. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Gibbons, in further view of Ono et al., is maintained. Takahara et al., and Gibbons, have been discussed above. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, no more than routine skill would have been required at the time of applicant invention to have used the Ono et al., hepatitis virus sequence, in the immunoassay of Takahara et al., and Gibbons, because Ono et al., teaches the complete nucleotide sequence which is important in the understanding of the genetic system.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JNH*

July 21, 2000

JGraser 7/21/00
JENNIFER GRASER
PATENT EXAMINER